

01803; e-mail: [mark.riley@faa.gov](mailto:mark.riley@faa.gov); telephone (781) 238-7758; fax (781) 238-7199, for more information about this AD.

#### Material Incorporated by Reference

(l) None.

Issued in Burlington, Massachusetts, on April 23, 2009.

**Peter A. White,**

*Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.*  
[FR Doc. E9-10145 Filed 5-4-09; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 510

[Docket No. FDA-2009-N-0665]

#### New Animal Drugs; Change of Sponsor's Name

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from IVX Animal Health, Inc., to Teva Animal Health, Inc.

**DATES:** This rule is effective May 5, 2009.

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: [david.newkirk@fda.hhs.gov](mailto:david.newkirk@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, has informed FDA that it has changed its name to Teva Animal Health, Inc. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect this change.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

#### PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600 in the table in paragraph (c)(1), remove the entry for "IVX Animal Health, Inc." and alphabetically add a new entry for "Teva Animal Health, Inc."; and in the table in paragraph (c)(2), revise the entry for "059130" to read as follows:

#### § 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * *	* * *
Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503	059130
* * *	* * *

(2) \* \* \*

Drug labeler code	Firm name and address
* * *	* * *
059130	Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503
* * *	* * *

Dated: April 29, 2009.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. E9-10262 Filed 5-4-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA-2009-N-0665]

#### Implantation or Injectable Dosage From New Animal Drugs; Change of Sponsor; Repository Corticotropin Injection

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Summit Hill Laboratories to Putney, Inc.

**DATES:** This rule is effective May 5, 2009.

#### FOR FURTHER INFORMATION CONTACT:

David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: [david.newkirk@fda.hhs.gov](mailto:david.newkirk@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 8-760 for ADRENOMONE (repository corticotropin injection U.S.P.) to Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101. Accordingly, the regulations are amended in 21 CFR 522.480 to reflect this change of sponsorship.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

#### § 522.480 [Amended]

■ 2. In paragraph (a)(2) of § 522.480, remove "037990" and add in its place "026637".

Dated: April 30, 2009.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. E9-10291 Filed 5-4-09; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 589**

[Docket No. FDA-2002-N-0031] (formerly Docket No. 2002N-0273)

RIN 0910-AF46

**Substances Prohibited From Use in Animal Food or Feed; Confirmation of Effective Date of Final Rule; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; confirmation of effective date; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule; confirmation of effective date, that appeared in the **Federal Register** of Friday, April 24, 2009 (74 FR 18626) (the April 24, 2009, final rule; confirmation of effective date). That document had confirmed the effective date of April 27, 2009, for a final rule that published in the **Federal Register** of April 25, 2008 (73 FR 22720), entitled “Substances Prohibited From Use in Animal Food or Feed.” In the April 24, 2009, final rule; confirmation of effective date, the agency also established a compliance date of October 26, 2009, in order to allow additional time for renderers to comply with the new requirements. The April 24, 2009, final rule; confirmation of effective date was published with an inadvertent error in the “Background” section. This document corrects that error.

**DATES:** This correction is effective: May 5, 2009.

**FOR FURTHER INFORMATION CONTACT:** Joyce A. Strong, Office of Policy, Planning, and Preparedness (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E9-9466, appearing on page 18626 in the **Federal Register** of Friday, April 24, 2009, the following correction is made:

On page 18626, in the third column, under “I. Background,” in the first paragraph, the first sentence “In the **Federal Register** of April 25, 2008, FDA published a final rule entitled “Substances Prohibited From Use in Animal Food or Feed)” (referred to herein as the April 25, 2008, final rule), that would become effective 1 year after the April 27, 2009, date of publication.” is corrected to read “In the **Federal Register** of April 25, 2008, FDA published a final rule entitled

“Substances Prohibited From Use in Animal Food or Feed” (referred to herein as the April 25, 2008, final rule), that would become effective 1 year after that publication.”

Dated: April 28, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-10138 Filed 5-4-09; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 601**

[Docket No. FDA-2009-N-0100]

**Revision of the Requirements for Publication of License Revocation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is clarifying the regulatory procedures for notifying the public about the revocation of a biologics license to be consistent with current practices. FDA is amending the regulations in accordance with the agency’s direct final rule procedures. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA’s usual procedures for notice and comment rulemaking to provide a procedural framework to finalize the rule in the event that we receive any significant adverse comments on the direct final rule. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

**DATES:** This rule is effective September 17, 2009. Submit written or electronic comments on or before July 20, 2009. If FDA receives no significant adverse comments within the specified comment period, the agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2009-N-0100, by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

**Written Submissions**

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under **Electronic Submissions**.

**Instructions:** All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Request for Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of January 25, 1977 (42 FR 4680), FDA issued a final rule revising, among other things, the procedures under part 601 (21 CFR part 601) for issuing, revoking, and suspending biologics licenses, and publishing license revocations. FDA revised these procedures in order to simplify and codify existing practices, establish new requirements where appropriate, and ensure that practices and procedures would be consistently applied throughout the agency.